



510(k) Summary

Submitted By:

Ben Lichtenwalner
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048
847-680-1000

APR 22 2010

Date Summary Prepared:

March 5, 2010

Device Name:

Classification Name - Gastrointestinal Tube and accessories
Common/Usual Name - Rectal Catheter
Proprietary Name - InstaFlo Bowel Catheter System Kit

Predicate Device:

The InstaFlo Bowel Catheter System Kit is a modification to the following device:

Product	510(k)
ActiFlo Indwelling Bowel Catheter System Kit	K083153

Device Description:

The InstaFlo Bowel Catheter System Kit contains two main parts: the catheter and the collection bag. The insertion end of the catheter contains a retention cuff and the other end of the catheter has a twist lock fitting to attach the collection bag. The retention cuff leads to a drain tube that allows stool to drain directly from the rectum into the bag. There are two catheter connectors attached to the catheter. The Blue connector is used to inflate and deflate the retention cuff. The Clear connector is used only to irrigate the device when needed.

Intended Use:

For diversion of liquid or semi-liquid stool to facilitate the collection of fecal matter in patients with little or no bowel control.

FUNCTION	ActiFlo Indwelling Bowel Catheter System Kit (Current Device)	InstaFlo Catheter System Kit (Modified Device)
Indications for Use	Diversion of fecal matter to minimize external contact with the patient, to facilitate the collection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enema/medications.	For diversion of liquid or semi-liquid stool to facilitate the collection of fecal matter in patients with little or no bowel control.
Kit Contents	<ul style="list-style-type: none"> • (1) ActiFlo Catheter • (1) 60cc Syringe • (2) 5g Packet Water Soluble Lube • (1) Drainable Collection Bag or (2) Closed Collection Bags • (2) Skin Barriers • (1) Irrigation Bag • (1) Instructions for Use 	<ul style="list-style-type: none"> • (1) InstaFlo Catheter • (1) 60cc Syringe • (1) Closed Collection Bag • (1) Instructions for Use • (1) Quick Reference Insertion Guide
Bowel Retention	External Balloon	External Balloon
Bowel Irrigation	Silicone funnel that is cath-tip syringe compatible; also comes with removable barbed connector for attachment to Luer-tip syringe.	Removing bowel irrigation indications from IFU. Irrigation bag will not be provided in kit. IRRG connection will only be recommended for irrigation of the bowel catheter tubing.
Port Access	Sampling / fluid administration	Sampling / fluid administration
Drainage Flow Suspension	Intraluminal (ARV) balloon	No Intraluminal (ARV) balloon.
Anti-Internal Migration	External silicone retention faceplate with anchor straps	Blue colored collapsible transphincteric zone to be used as a visual indicator
Flush / Stool Sampling	Mid-line silicone access port compatible with catheter tip syringe	Mid-line silicone access port compatible with catheter tip syringe
Enema / Medication Administration	Silicone funnel that is cath-tip syringe compatible; also comes with removable barbed connector for attachment to Luer-tip syringe.	Removing the instructions for Enema / Medication Administration from IFU to simplify usage of the device. An irrigation bag will not be supplied in the InstaFlo kit.
Sterile	Non-Sterile	Non-Sterile

Performance Testing Conclusions:

Biocompatibility testing was performed based on the United States Food and Drug Administration Office of Device Evaluation General program Memorandum #G95-1 and ISO 10993 biocompatibility testing standards. Product evaluation supports acceptability of the device for its intended clinical use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Mr. Benjamin Lichtenwalner
Senior Regulatory Affairs Specialist
Hollister Incorporated
2000 Hollister Drive
LIBERTYVILLE IL 60048

APR 22 2010

Re: K100273

Trade/Device Name: InstaFlo Bowel Catheter System Kit
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: March 22, 2010
Received: March 23, 2010

Dear Mr. Lichtenwalner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

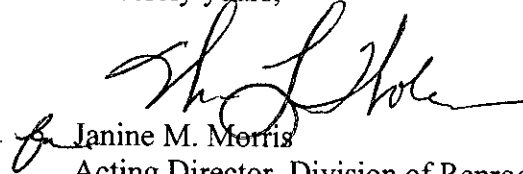
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K100273

Device Name: InstaFlo Bowel Catheter System Kit

Indications for Use:

For diversion of liquid or semi-liquid stool to facilitate the collection of fecal matter in patients with little or no bowel control.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K100273